Ex 15 - CAH_MDL2804_02465982-6053

Plaintiffs' Opposition to Defendants' Motion for Summary Judgment on Proximate Causation Grounds

DEA ISO for Swedesboro

U.S. Department of Justice
Drug Enforcement Administration

Office of the Deputy Administrator *Washington, D.C. 20537*

IN THE MATTER OF

DEC 0 7 2007

Cardinal Health
1120 Commerce Blvd.
Swedesboro, NJ 08085

ORDER TO SHOW CAUSE AND IMMEDIATE SUSPENSION OF REGISTRATION

PURSUANT to Sections 303 and 304 of the Controlled Substances Act, Title 21, United States Code, Sections 823 and 824,

NOTICE is hereby given to inform Cardinal Health ("Respondent") of the immediate suspension of Drug Enforcement Administration ("DEA") Certificate of Registration RW0269654, pursuant to 21 U.S.C. § 824(d), because Respondent's continued registration constitutes an imminent danger to the public health and safety. DEA Certificate of Registration RW0269654 is assigned to Cardinal Health's Swedesboro, New Jersey, Distribution Center. Notice is also given to afford Respondent an opportunity to show cause before DEA, at DEA Headquarters located at 600 Army Navy Drive, Arlington, Virginia, on April 7, 2008 (if Respondent requests such a hearing), as to why DEA should not revoke such registration pursuant to 21 U.S.C. § 824(a)(4), and deny any pending applications for renewal or modification of such registration pursuant to 21 U.S.C. §§ 823(b) and (e), because Respondent's continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. §§ 823(b) and (e). The basis for this Order to Show Cause and Immediate Suspension of Registration is set forth in the following non-exhaustive summary of facts.

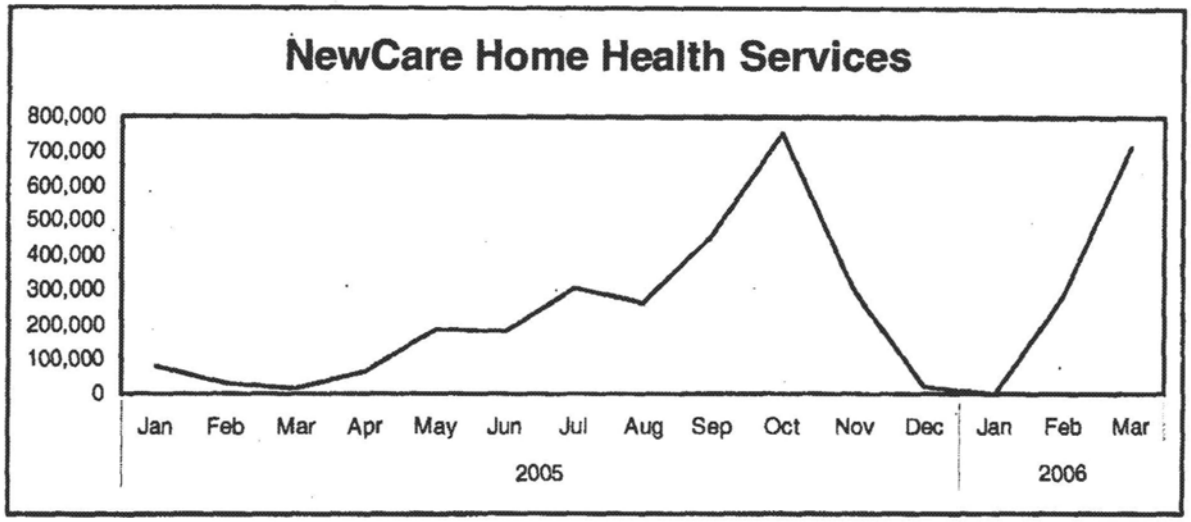
1. Respondent is registered with DEA as a distributor in Schedules II-V under DEA number RW0269654 at 1120 Commerce Blvd., Swedesboro, New Jersey 08085. DEA number RW0269654 will expire on May 31, 2008.

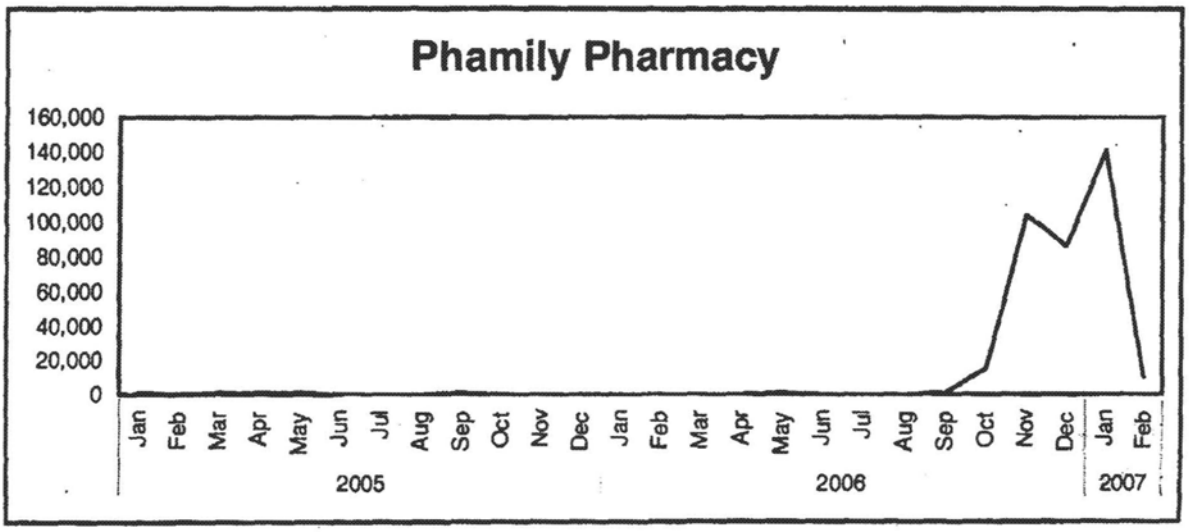
2. Respondent has failed to maintain effective controls against the diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels, in violation of 21 U.S.C. §§ 823(b)(1) and (e)(1). From January, 2005 through August, 2007, Respondent distributed over 4.5 million dosage units of combination hydrocodone products to customers that it knew or should have known were diverting hydrocodone into other than legitimate medical, scientific and industrial channels. Hydrocodone, in the formulation that Respondent distributed to these customers, is a Schedule III narcotic controlled substance that is addictive and widely abused.

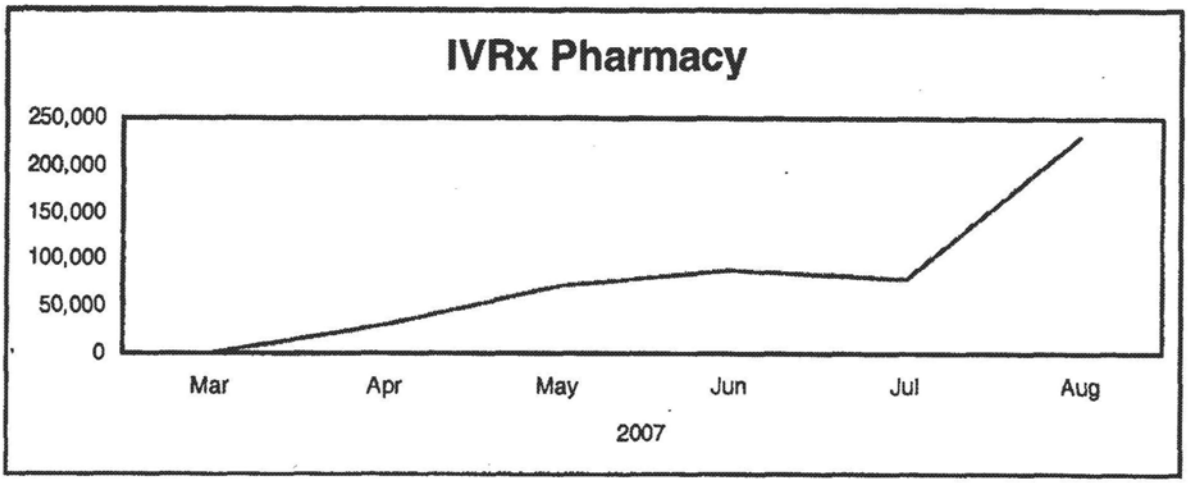
3. Some of Respondent's largest purchasers of combination hydrocodone products were pharmacies engaged in a scheme to distribute controlled substances based on purported

prescriptions that were issued for other than a legitimate medical purpose and by physicians acting outside the usual course of professional practice. These pharmacies distributed millions of dosage units of hydrocodone based on illegitimate prescriptions originating from drug distribution websites, in violation of applicable Federal and State law. *See United Prescription Services, Inc.*, 72 Fed. Reg. 50,397 (2007).

4. Respondent repeatedly distributed hydrocodone combination products to pharmacies engaged in the diversion of controlled substances, i.e., NewCare Home Health Services, Phamily Pharmacy and IVRx Pharmacy. Respondent continually supplied these pharmacies with excessive amounts of hydrocodone under circumstances in which Respondent knew or should have known that these pharmacies were diverting hydrocodone into other than legitimate medical, scientific, and industrial channels. The following graphs reflect the total dosage units of hydrocodone combination products that Respondent distributed to each pharmacy.







5. Respondent distributed hydrocodone to the pharmacies identified in paragraph 4, above, even though Respondent knew that many of the orders placed by the pharmacies were of an unusual size and were "suspicious" as that term is used in 21 C.F.R. § 1301.74(b). Respondent distributed hydrocodone to each of the named pharmacies even though the pharmacies ordered few, if any, other drug products from Respondent. Respondent knew that pharmacies generally order a wide variety of controlled substances and other drug products from wholesale distributors. Respondent also knew that orders that deviate substantially from a normal pattern were "suspicious" as that term is used in 21 C.F.R. § 1301.74(b). Respondent distributed hydrocodone to each of the named pharmacies even though the pharmacies ordered hydrocodone more frequently than Respondent's other pharmacy customers. Respondent knew that orders of unusual frequency were "suspicious" as that term is used in 21 C.F.R. § 1301.74(b).

6. Respondent repeatedly supplied the pharmacies named in paragraph 4, above, with excessive amounts of hydrocodone despite the substantial guidance provided to Respondent by DEA regarding identifying rogue pharmacies engaged in Internet diversion schemes, and despite the public information readily available to Respondent regarding the pharmacies' association with drug distribution websites, and despite the suspicious nature of the orders placed by these pharmacies. *See Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487 (2007).

IN view of the foregoing, and pursuant to 21 U.S.C. §§ 823(b), (e), and 824(a)(4), it is my preliminary finding that Respondent has failed to maintain effective controls against diversion and that the continued registration of Respondent would be otherwise inconsistent with the public health and safety. Moreover, it is my preliminary conclusion that Respondent's continued registration while these proceedings are pending would constitute an imminent danger to the public health and safety because of the substantial likelihood that Respondent will continue to divert large quantities of controlled substances. Accordingly, pursuant to the provisions of 21 U.S.C. § 824(d) and 21 C.F.R. § 1301.36(e), and the authority granted me under 28 C.F.R. § 0.100, DEA Certificate of Registration RW0269654 is hereby suspended, effective December 13, 2007, at 12:00 p.m. Eastern Standard Time. Such suspension shall remain in effect until a final determination is reached in these proceedings.

PURSUANT to 21 U.S.C. § 824(f) and 21 C.F.R. § 1301.36(f), the Special Agents and Diversion Investigators of the DEA who serve this Order to Show Cause and Immediate Suspension of Registration are authorized to place under seal or to remove for safekeeping all controlled substances that Respondent possesses pursuant to its registration, upon the effective date of the immediate suspension of Respondent's registration. The said Agents and Investigators are also directed to take into their possession Respondent's DEA Certificate of Registration and any unused order forms.

THE following procedures are available to Respondent in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension, Respondent may file with the Deputy Administrator of the DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. (*See* 21 C.F.R. § 1301.43(a)). If Respondent fails to file such a request, the hearing set for April 7, 2008, shall be cancelled in accordance with paragraph 3, below.

2. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, Respondent may file with the Deputy Administrator a waiver of hearing together with a written statement regarding Respondent's position on the matters of fact and law involved. (*See* 21 C.F.R. §1301.43(c)).

3. Should Respondent decline to file a request for a hearing or, should Respondent request a hearing and then fail to appear at the designated hearing, Respondent shall be deemed to have waived the right to a hearing and the Deputy Administrator may cancel such hearing, and may enter her final order in this matter without a hearing and based upon the investigative file and the record of this proceeding as it may then appear. (*See* 21 C.F.R. §§ 1301.43(d), 1301.43(e)).

Correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, Washington, D.C. 20537. Matters are deemed filed upon receipt by the Hearing Clerk. (*See* 21 C.F.R. § 1316.45).

Michele M. Leonhart 12/7/07
Deputy Administrator
Drug Enforcement Administration

cc: Hearing Clerk
Office of Administrative Law Judges

APPENDIX E

DEA Show Cause for Houston

U. S. Department of Justice
Drug Enforcement Administration

www.dea.gov

Washington, D.C. 20537

JAN 3 0 2008

IN THE MATTER OF

Cardinal Health
13651 Dublin Court
Stafford, Texas 77477

ORDER TO SHOW CAUSE

PURSUANT to Sections 303 and 304 of the Controlled Substances Act, Title 21, United States Code, Sections 823 and 824,

NOTICE is hereby given to afford Cardinal Health ("Registrant") an opportunity to show cause before the Drug Enforcement Administration ("DEA"), at DEA Headquarters located at 600 Army Navy Drive, Arlington, Virginia, at a place and time to be determined, (if Registrant requests such a hearing), as to why DEA should not revoke DEA Certificate of Registration, RC0333524, pursuant to 21 U.S.C. § 824(a)(4), and deny any pending applications for renewal or modification of such registration pursuant to 21 U.S.C. §§ 823(b) and (e), because Registrant's continued registration is inconsistent with the public interest. DEA Certificate of Registration RC0333524 is assigned to Cardinal Health's Stafford, Texas Distribution Center. The basis for this Order to Show Cause is set forth in the following non-exhaustive summary of facts.

1. Registrant is registered with DEA as a distributor in Schedules II-V under DEA number RC0333524 at 13651 Dublin Court, Stafford, Texas 77477. DEA number RC0333524 will expire on May 31, 2008.

2. Registrant distributed massive amounts of particular controlled substances to retail pharmacy customers without maintaining adequate controls to detect and prevent the diversion of controlled substances. For example, from January 2007 through September 2007, Registrant distributed nearly 21 million dosage units of hydrocodone to its retail pharmacy customers. Despite distributing such a large quantity of hydrocodone – a highly addictive and widely abused schedule III controlled substance – Registrant did not have sufficient policies and procedures in place to detect and prevent diversion; did not execute those policies and procedures that were in effect; and failed to provide its employees with the necessary training and resources to detect and prevent diversion.

3. Registrant's distributions of controlled substances to Richmond Pharmacy, AK Pharmacy, and others, were under circumstances that clearly indicated that the pharmacies were engaged in the widespread diversion of controlled substances.

4. Notwithstanding the large quantities of controlled substances ordered by these pharmacies, Registrant failed to conduct meaningful due diligence to ensure that the controlled substances were not diverted into other than legitimate channels. Moreover, Registrant continued to supply the pharmacies with controlled substances without conducting due diligence, notwithstanding that the pharmacies were ordering controlled substances in quantities that far exceeded what traditional retail pharmacies order; that the pharmacies were ordering controlled substances on a more frequent basis than Registrant's traditional retail pharmacy customers; and that Registrant was supplying an inordinate amount of controlled substances versus non-controlled substances to these pharmacies.

5. The direct and foreseeable consequence of Registrant's failure to conduct appropriate due diligence was the likely diversion of millions of dosage units of particular controlled substances.

6. Despite Registrant's policy limiting a retail pharmacy customer's purchases of hydrocodone products to 800 dosage units a day, Registrant frequently distributed hydrocodone in quantities that greatly exceeded this limit. Registrant, however, rarely scrutinized these purchases, and in the few instances where Registrant investigated a particular order, it was frequently done by employees with little or no training in the prevention and detection of diversion and/or by employees with a direct financial interest in the successful completion of the transaction.

7. From January 2, 2007 through September 11, 2007, Registrant distributed approximately 1,381,500 dosage units of hydrocodone to Richmond Pharmacy, or approximately 160,000 dosage units each month. During that period, Registrant distributed hydrocodone to Richmond on 142 days. On each of those days, Richmond's purchase of hydrocodone exceeded the daily limit set by Registrant for its retail pharmacy customers. More recently, on each of the eight days in September in which Registrant shipped hydrocodone to Richmond, Richmond grossly exceeded Registrant's threshold of hydrocodone distributions without scrutiny by Registrant's employees. Registrant distributed 66,000 dosage units of hydrocodone to Richmond on September 4, 2007; 6,000 dosage units on September 5, 2007; 12,000 dosage units on September 6, 2007; 18,000 dosage units on September 7, 2007; 48,000 dosage units on September 10, 2007; 24,000 dosage units on September 11, 2007; and 12,000 dosage units on September 12, 2007. Additionally, on September 17, 2007, Registrant shipped 12,000 dosage units of hydrocodone to Richmond, despite having been notified on September 14, 2007, that Richmond surrendered its DEA registration on September 13, 2007, and was no longer authorized to order or dispense controlled substances.

8. Registrant likewise failed to scrutinize the ordering practices of other retail pharmacy customers who exceeded their monthly limit of hydrocodone purchases and other controlled substances, and continued to distribute massive amounts of controlled substances to these customers despite the fact that these customers routinely exceeded, by huge margins, their monthly limit for purchases of particular controlled substances.

THE following procedures are available to Registrant in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause Registrant may file with the Deputy Administrator of the DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. (*See* 21 C.F.R. § 1301.43(a)). If Registrant fails to file such a request, the hearing shall be cancelled in accordance with paragraph 3, below.

2. Within 30 days after the date of receipt of this Order to Show Cause, Registrant may file with the Deputy Administrator a waiver of hearing together with a written statement regarding Registrant's respective positions on the matters of fact and law involved. (*See* 21 C.F.R. §1301.43(c)).

3. Should Registrant decline to file a request for a hearing or, should Registrant request a hearing and then fail to appear at the designated hearing, Registrant shall be deemed to have waived the right to a hearing and the Deputy Administrator may cancel such hearing, and may enter her final order in this matter without a hearing and based upon the investigative file and the record of this proceeding as it may then appear. (*See* 21 C.F.R. §§ 1301.43(d), 1301.43(e)).

Correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, Washington, D.C. 20537. Matters are deemed filed upon receipt by the Hearing Clerk. (*See* 21 C.F.R. § 1316.45).

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

cc: Hearing Clerk
Office of Administrative Law Judges

APPENDIX F

2008 Settlement Agreement - Civil Case

SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into by and between the United States Department of Justice, through the United States Attorney's Offices for the Districts of New Jersey, Middle Florida, Southern Texas, Western Washington, Colorado, Northern Georgia, and Central California ("United States") and Cardinal Health, Inc., for itself and on behalf of its subsidiary entities which hold the registrations listed in Attachment A to this agreement (collectively "Cardinal") (each a "Party" and collectively the "Parties").

RECITALS

1. Cardinal is in the business of distributing branded and generic prescription drugs, as well as over-the-counter medications, to retail pharmacies throughout the United States. In furtherance of this business objective, Cardinal operates numerous distribution facilities in the United States, including the seven facilities more fully described in Attachment B to this Agreement ("the Seven Facilities").

2. As described in Attachment A, Cardinal holds Certificates of Registration issued by the Drug Enforcement Administration ("DEA") authorizing it to distribute controlled substances from each of its distribution facilities that handle controlled substances, including the Seven Facilities described in Attachment B.

3. Cardinal is required to operate the Seven Facilities in accordance with the statutory and regulatory provisions of the Controlled Substances Act, 21 U.S.C. § 801 *et seq.* ("the CSA").

4. Each of the Seven Facilities supplies prescription medications, including controlled substances, to retail pharmacies and other health care providers within the respective jurisdictions as stated in Paragraph 8.

5. DEA is the Department of Justice component agency primarily responsible for administering the CSA and is vested with the responsibility of investigating CSA violations.

6. The Attorney General, through the United States Attorneys, has primary authority to bring civil actions to enforce the CSA in the Districts noted above. *See* 21 U.S.C. § 871 *and* 28 C.F.R. § 0.55(c).

7. Hydrocodone is a medication whose manufacture, distribution, sale and possession is regulated by DEA under the CSA. This includes a requirement to report customer orders for controlled substances that are suspicious as the term is defined under 21 C.F.R. §1301.74(b).

8. The "Covered Conduct" shall mean the following alleged conduct:

A. Within the District of New Jersey: From January 2005 through August 2007, Cardinal-Swedesboro sold more than 4.5 million dosage units of hydrocodone to three pharmacies (IVRx Pharmacy in Springfield, New Jersey; Newcare Home Health Services in Baltimore, Maryland; and Phamily Pharmacy in Washington, D.C.), and failed to report these sales as suspicious orders to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5);

B. Within the Middle District of Florida: From August 2005 through October 2007, Cardinal-Lakeland sold more than 8 million dosage units of hydrocodone to ten pharmacies in the Tampa area (Medipharm-Rx, Inc., DRM Enterprises, Inc., Jen-Mar Pharmacy Services, Inc., Armenia Pharmacy, Inc., National Pharmacy, Inc., Parulmed Corporation, Q-R-G-, Inc., RKR Holdings, Inc., United Prescription Services, Inc., and Satellite Drug and Pharmacy) and failed to report these sales as suspicious orders to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5);

C. Within the Southern District of Texas: From March 2006 through September 2007, Cardinal-Stafford sold more than 7.5 million dosage units of hydrocodone to fifteen pharmacies in the Houston area (Richmond Pharmacy, AK Pharmacy, Farmacia de Medica, Parkway Pharmacy, Farmacia del Pueblo, Magnum Road Pharmacy, Mastery Pharmacy, Amex Pharmacy #3, Local Pharmacy, HP Pharmacy, I-10 East Pharmacy, Xavier Pharmacy, TXRX Pharmacy, Park Place Pharmacy, and King's Pharmacy) and failed to report these sales as suspicious orders to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5);

D. Within the Western District of Washington: From March 2007 through November